EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO:	
Angela Daugherty and Jimmy Daugherty v. Ethicon, Inc., et al.	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Case No. 2:12-cv-02076	(General TVT-O)

The Video Deposition of MICHAEL KARRAM, M.D., taken by the Plaintiff, pursuant to Notice and Subpoena, before Teresa A. Moore, a Registered Professional and Certified Realtime Reporter, at the offices of Frost Brown Todd LLC, 301 East Fourth Street, Great American Tower, Suite 3300, Cincinnati, Ohio 45202, on Tuesday, June 28, 2016, at 4:18 p.m.

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MICHAEL KARRAM, M.D.,
of lawful age, a Witness herein, after having been first duly sworn, was examined and deposed as follows:

EXAMINATION

BY MR. ZONIES:

Q. Good afternoon, Dr. Karram. How are you?

A. I'm fine.

Q. My name is Joe Zonies. We've had the opportunity to speak before about three months ago, in your last deposition, at least the last one where I was taking the deposition.

Do you recall that deposition?

A. Was it on the TVT report?

Q. Yes, it was.

A. Do you have a brother at Ohio State, or something from Ohio State, or any relation; or is that not -- you're not the same guy?

Q. My brother went to Ohio State.

A. There you go. Yes, I do remember you.

Q. And you diagnosed me with a prostate problem.

A. I didn't. I said, it may be in a differential diagnosis you want to check out.

Q. That's correct. For what it's worth, I'm getting my BPH done shortly.

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A. Also, I remember a female sitting over here, not a male. What happened?
Q. Yeah, Shea travels with me.
A. I gotcha.
Q. And you get stuck with Greg today.
A. All right.
Q. You have the pleasure of being with Greg today.
Doctor, I'm going to have Greg or the court reporter hand you Exhibit 1, which is the Amended Notice of Deposition in this case.
Do you have that in front of you?
(Exhibit 1 marked for identification.)
A. I do.
Q. And have you seen that document before --
A. Yes, I have.
Q. -- or some version of it?
A. Some version of it, yes, I have.
Q. Okay. And you understand that you're here today to give your deposition concerning the TVT-O device; is that right?
A. That's correct.
Q. And what does "TVT-O" stand for?
A. Transvaginal tape obturator.

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Q. And have you, Dr. Karram, ever used Ethicon's TVT-O device?
A. Yes.
Q. When did you begin using it?
A. When it first came out.
Q. So somewhere around 2003 and 2004?
A. That sounds about right, yes.
Q. And did you receive training on the TVT-O device?
A. Yes, I did.
Q. What was your training?
A. I scrubbed on some cases with my brother.
Q. And your brother is whom?
A. Mickey Karram.
Q. Do you recall how many cases you scrubbed in on?
A. We actually -- he did a course at UC, where we did a cadaver lab, and then I scrubbed with him on five cases.
Q. And after scrubbing with him on five cases, did you then start putting in TVT-Os on your own?
A. Yes.
Q. What device were you using to treat stress urinary incontinence before the TVT-O?

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A. Retropubic TVT.
Q. By Ethicon?
A. Yes.
Q. Have you ever used any other transobturator device, other than Ethicon's TVT-O?
A. Yes, I have.
Q. What devices have you used?
A. I've used the Monarc. And that is the only transobturator that I've used, other than TVT-O and TVT Abbrevo. But you're talking other than Ethicon products?
Q. Well, you've used -- to treat women with stress urinary incontinence --
A. Yes.
Q. -- using the transobturator approach, you've used Ethicon's TVT-O, you've used the Monarc device, and you've used TVT Abbrevo by Ethicon; is that right?
A. Correct.
Q. What period of time did you use the Monarc?
A. I still use it to this day -- well, I'm sorry. It's going off the market. But up 'til the time Astora said they're not going to supply the Monarcs, I have still used them.
Q. And can you describe for me the differences

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between the Monarc and the TVT-O?
A. Yeah. The Monarc is an outside-in approach and the TVT-O is an inside-out approach.
Q. What would make -- were you using both the Monarc and TVT-O at the same time, in your practice?
A. Yes. I still do.
Q. Well --
A. Well -- yeah, go ahead.
Q. -- you use the TVT Abbrevo and the Monarc; is that fair?
A. Now?
Q. Yes.
A. Actually, since we've spoken, we now carry TVT-O. And so I use it again. I think, if you remember right, when you asked me that question, I thought that TVT-O was not manufactured anymore or sold anymore. But, in reality, I found out that it has, so we now stock it on our shelves. So we have TVT-O, TVT Abbrevo, and Monarc, and --
Q. So I'd like to --
A. Yeah.
Q. -- talk first about your choice between the TVT-O and Monarc --
A. Okay.

Q. -- recognizing that the TVT-O is inside-out and the Monarc is outside-in.

What clinical decision process do you go through when choosing whether to use the Monarc or the TVT-O?

A. Well, the patient has to be a patient that we would consider a good candidate for an obturator approach, which would be somebody with primary hypermobile stress urinary incontinence, no evidence of intrinsic sphincter deficiency. If she has mixed incontinence, then we would probably use an obturator approach versus a retropubic approach.

So it is probably, I would say, my go-to -- the obturator approach is my go-to procedure in approximately 70 to 75 percent of my cases.

Q. Okay. And when you're -- when the patient is, in your opinion, indicated for an obturator approach, how do you decide whether to use the TVT-O or the Monarc?

A. A lot of it has to do with the anatomy. It depends on their pelvic anatomy. It depends on the anatomy of the groin, their size, weight. And also, we're a training facility. So we have to train residents and fellows, and we always like to make sure

that they understand and are fluent in both an inside-out and an outside-in.

Q. And so one of the considerations that you mentioned was, it depends on the pelvic and groin anatomy, whether you're going to use Monarc or the TVT-O.

Can you tell me, when do you believe that the Monarc is the better choice of a device, related to the anatomy?

A. I wouldn't -- oh, I wouldn't say it's a better choice. I would say it's an alternative choice. And if somebody has a very, very large adipose internal groin area, I would probably use -- or I would use an inside-out TVT-O, versus somebody who is thin and the musculature is not an issue.

Q. And so it sounds like if a woman is obese or a large woman, that you have a preference for using the TVT-O over the Monarc; is that correct?

A. That's hard to quantify. I mean, I think they're interchangeable. What I like about the TVT-O is the fact that we want to place these slings midurethral. And so, from an anatomical standpoint, if you start at the midurethra, it's a lot more accurate to be midurethral in placement than if you start outside and

try to find the midurethra with your finger.

Q. So I guess my question would be: Why would you ever choose to use the Monarc over the TVT-O?

A. If you're at a hospital facility that doesn't have TVT-O and Monarc is the only obturator sling.

Q. Any other reason?

A. No.

Q. Do you believe that the Monarc and the TVT-O are essentially interchangeable on safety and effectiveness?

A. I think they're interchange -- well, no. No, it depends on the implanter.

Q. Tell me what that means.

A. Well, I've seen people that utilize the Monarc or, vice versa, the TVT-O, and they put it in incorrectly and it's not going to be effective, or they're going to have more problems. In my hands, they're interchangeable, if my opinion.

Q. So, would it be fair to say that in an index-type patient with a capable physician, that you believe, it is your opinion that the Monarc and the TVT-O are equivalent for purposes of safety and efficacy?

A. Efficacy, yes. Safety, again it depends on

the implanter. But, yes, if the implanter is an experienced implanter and has experience with both of the products, I would say yes.

Q. You also utilize the TVT Abbrevo for an obturator approach. Do you still use that today?

A. I do.

Q. What do you find to be the advantages of the Abbrevo over the TVT-O?

A. Less groin pain.

Q. Any other advantages?

A. It's pretty much the same. It has -- it leaves less mesh in the patient, and, therefore, less mesh in the groin area and possible mesh in the adductor muscles.

Q. And why is that a benefit of the Abbrevo over the TVT-O?

A. If you have a longer mesh in the patient, then you might have a higher incidence of putting a mesh in one of the adductor muscles, and that can give you, maybe, a prolonged groin pain.

Q. And you've actually experienced that with patients of yours, using the TVT-O device, that they've had prolonged groin pain?

A. No, I haven't. But I've seen that in the

literature.
Q. Any other differences between the TVT Abbrevo and the TVT-O that inform your clinical decision about which device to use?
A. The TVT-O has more data, because Abbrevo came out earlier -- or later, I'm sorry.
Q. And you've actually been using the TVT Abbrevo for over five years; is that right?
A. Correct, when it first came out.
Q. Again, I'll ask the question I asked with TVT-O and Monarc, which is: In an index patient, all things being equal, would you choose the TVT Abbrevo over the TVT-O?
A. I would say they are interchangeable, in my hands.
Q. And would you agree that the TVT-O did -- sorry.
Would you agree that the studies have reflected that there is, indeed, less groin and thigh pain with the TVT Abbrevo, as compared to the TVT-O, across patient populations and different physicians?
A. I am aware of some scientific data that shows that, yes.
Q. And do you agree with that, across the

populations and in different physicians' hands, that the TVT Abbrevo demonstrates less groin and thigh pain than the TVT-O?
A. I would say there is some data to support that, yes.
Q. And is that your opinion in this case?
A. My opinion is based on how I implant the TVT-O and how we teach the implanter to implant. And, in my hands, I have not seen a difference.
Q. Well, your opinion, in this case, is based upon not just upon your own personal experience; correct?
A. That's correct.
Q. Your opinion is based upon your personal experience and also your review of the scientific literature; is that correct?
A. That is correct.
Q. And would you agree that considering both your experience and the overall scientific literature, that the TVT Abbrevo is associated with less groin and thigh pain than is a TVT obturator?
A. Yes.
Q. When discussing the -- when you believe that a patient has an indication for the obturator

approach -- do you remember that earlier in your testimony?
A. That's correct, yes, I do.
Q. One of the -- if a patient presents with ISD or severe ISD, isn't it true that your choice of treatment, when looking at meshes, would be a retropubic approach?
A. In the majority of cases, yes.
Q. And is it your opinion, Doctor, that the TVT-O would not be the first-line choice of treatment for a woman with severe ISD?
A. In my opinion, that is correct, yes.
Q. That if a woman presents with severe ISD, it's your belief that, and opinion that, the retropubic approach would be the standard of care; correct?
A. It depends on how you define "the standard of care."
Q. Well, okay. So let me take it out of standard of care. Thank you for that.
A. Okay. Uh-huh.
Q. Doctor, it's your opinion that when a woman presents with severe ISD, that the TVT retropubic or a retropubic approach is the correct treatment for that incontinence; is that correct?

A. Again, it depends on what you consider correct. And I'm not trying to be antagonistic. But in my opinion, if a patient presents with severe ISD, I will, under almost all circumstances, other than maybe contraindications to a retropubic -- that I would put in a retropubic. However, I wouldn't fault a physician for putting in a transobturator in somebody who has severe ISD, if they feel that they can get the appropriate urethral resistance with that procedure in their hands.
Does that make sense?
Q. It does.
A. Okay, good.
Q. I appreciate that.
Doctor, do you believe that there are scientific literature that supports the conclusion that a retropubic approach is a better choice, if it's available, than an obturator approach, if a woman has severe ISD?
A. Yes, I think there is literature to support that thought.
Q. And what literature would you cite for that? Do you know off the top of your head?
A. I think the -- I don't know if they looked at ISD, specifically, in the TOMUS Study, which was the

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transobturator midurethral sling study, that they looked at transobturator versus TVT. I can't cite you a study right now, but I know there have been studies that have come out, currently and in the past, where they have looked at ISD patients and transobturator patients and have found a higher success rate with TVT retropubic than transobturator, in ISD patients.

Q. Now, you said that you do some training at your facility; is that right?

A. That's correct.

Q. When you are training your residents on use of slings, do you discuss with them your belief that retropubic is a better approach when a woman has ISD?

A. I do.

Q. And do you explain to them that your choice, in such instances, would be a retropubic approach over an obturator approach, as long as it's -- both are -- as --

A. Yes.

Q. -- long as the retropubic is possible?

A. Yes.

Q. Do you believe that's important information to communicate to those residents about their treatment of their patients?

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A. I do.

Q. And it's critical to patient safety that you communicate that to those residents, so that they can properly treat and inform and consent women for a sling operation, when they have ISD; correct?

MR. WALKER: Object to form.

A. Could you ask the question -- the safety part of it, yes, I agree. But, as I mentioned before, I will also instruct them that, in certain circumstances, you can still put in a transobturator to treat ISD, but you have to make sure that you put it in differently than a hypermobile urethra stress incontinence patient.

Q. So when you say "put it in differently," in other words, when you're treating a woman with ISD -- let me ask if this is a fair summary of what you're saying, Doctor, of your opinion.

When you're treating a woman with severe ISD, your first-line choice would be a retropubic approach; however, an obturator approach would be possible, but you have to essentially place the sling differently than one would normally do; is that fair?

A. You have to -- you have to do whatever it takes to increase the urethral resistance, because that's what you're trying to do, when somebody has an

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ISD, is increase their urethral resistance, however that may be. You know, that's surgeon preference. But there are surgeons that can use that -- the transobturator approach and put it in exactly as it's meant to be and as it's described to be placed, and get a higher urethral resistance.

Q. Why is it important for you to instruct your residents in that way?

A. Well, because when they go out into practice, I want them to be aware of the different types of incontinence; I want them to be aware of the treatments. And obviously, you know, the first treatment that is successful is better for the patient than to need a repeat procedure to correct her problem.

Q. And you -- so your advice on this issue, to your residents, is focused on patient safety and using the most effective method to treat their ISD; correct?

MR. WALKER: Object to form.

A. Yes, correct.

Q. And that's why you teach your residents that, so that they, in turn, can treat their patients with the same level of competence, safety, and efficacy; correct?

MR. WALKER: Object to form.

A. Yes.

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Q. And if you were in a position to inform other physicians, across the country, of your beliefs about treatment of ISD, this is consistent with what you would tell those physicians; correct?

A. If I was giving a lecture on stress urinary incontinence to a group of physicians and we were talking about the different slings that I use for ISD, then I would say my preference, under most circumstances, if it's possible, is to do a retropubic, yes.

Q. And that preference of yours is grounded in sound scientific literature, as well; correct?

A. There is literature to support the fact that the retropubic does a better treatment of ISD than a transobturator, yes.

Q. And when you have a discussion with your patients about ISD and treating their ISD, Doctor, do you have a -- do you inform those patients, as well, that you believe a retropubic approach has better outcomes associated with it, for ISD, than does an obturator approach?

MR. WALKER: Object to form.

A. I discuss that in the context of what are the available therapies for their problem, and what is the

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safest, and what are the pros and cons to each, and what I think is the best. But the best may have a higher risk of complications, may have a higher risk of other issues. And so I will say, and we can use a different approach that is safer and may give you as good a result. But I inform them of both procedures, correct.

Q. And why do you do that? Why do you inform your patients of that?

A. I think because, whenever you're treating somebody surgically, it's a combined decision between the physician and the patient. And they have just as much say-so in it as you do, as long as you've explained to them and they understand what you've explained to them.

Q. And your patients and, frankly, all patients are entitled to know that there -- one of these treatments, retropubic, may be more effective and potentially safer than the TVT-O for treatment of ISD; correct?

MR. WALKER: Object to form.

A. I think it's important to discuss all the options, all the risks, benefits, and then come to a mutual decision.

Q. Now, Doctor, along the same vein, when you're

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having a discussion with your patients about whether to use the TVT-O full-length sling or the TVT Abbrevo, what considerations do you tell them between those two devices?

A. I say they're -- the results, in my hands, are equal; there is data to support that there is less groin pain with the TVT Abbrevo than the TVT-O; and that the safety profile is the same, other than the pain, shown by certain scientific evidence; and -- but the results should be equal.

Q. You would agree, Doctor, that the scientific literature is clear that the TVT Abbrevo inflicts less groin/thigh pain than does the TVT obturator; correct?

MR. WALKER: Object to form.

A. I wouldn't say it's perfectly clear. I would say that there is data to support that.

Q. Doctor, the pain that's associated with the TVT obturator --

A. Yes.

Q. -- and also the Monarc, what is your opinion, what causes that pain?

MR. WALKER: Object to form.

And I'm sorry to interrupt. I mean, what specific pain are you referring to?

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Q. So, Doctor --

A. Yes.

Q. -- the thigh and groin pain that is associated with the TVT-O, what is it that you believe, your opinion, causes that pain?

A. There's more than one issue. There's more than one reason.

Q. What are the reasons?

A. Okay. It could be that they injure the adductor muscles as they're trying to introduce the sling into the appropriate area. That would be the first.

Number two, it could be that they injure the periosteum of the bone when they're inserting the device.

Number three, they could be putting the sling out too far lateral and possibly irritating the anterior division of the obturator nerve.

Those are probably the three most commonly-held reasons why people get obturator pain.

Q. Have you ever treated a complication associated with a TVT-O device?

A. Yes, I have.

Q. How often have you done that?

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A. I can't give you the exact number. But I've done it -- I don't want to say quite a few times. I mean, I don't know how you want me to quantify that. I can't give you a number. But I have definitely treated TVT-O complications.

Q. And what do you believe to be the most common indication for your treating the TVT-O complication?

A. A vaginal erosion.

Q. And what is your -- have you ever treated a TVT-O patient, where the complication was pain, groin and thigh pain --

A. I have. Sorry. I have.

Q. And what was your treatment course for such a patient?

A. First, it was physical therapy with medications and certain exercises and activities; and then it was injections, point injections to the area; and, lastly, there have been times where I've had to excise some of the sling.

Q. And did you find that when you excised some of the TVT-O sling, that, indeed, the pain resolved?

A. No.

Q. Pain continued even after you took out a portion of the sling; is that right?

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A. In some cases, yes.
Q. So you have experienced a number of patients where the pain associated with the use of a TVT-O device was long-term chronic pain; is that correct?
A. I have seen patients with long-term chronic pain, yes.
Q. And in some of those patients, that long-term chronic pain didn't resolve even after you took out portions of the mesh; is that correct?
A. That's correct.
Q. If a -- in those patients who were suffering from long-term chronic pain would not resolve when you excised some of the TVT-O mesh, was there any further treatment or did they just have to live a life of pain?
A. No, there was further treatment.
Q. What was the further treatment?
A. Physical therapy.
Q. So more physical therapy and more injections, even after the excision?
A. More physical therapy, less injections.
Q. And do you have some patients where even that physical therapy ultimately could not resolve the pain and they continue, to this day, to be in pain?
MR. WALKER: Object to form.

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A. No, I don't have any of those. All the patients that I have seen and treated with the treatment modalities that we have just elicited, with time, have all resolved.
Q. And that's assuming that those patients continued to see you for follow-up; correct?
A. Yes. I wouldn't know what happens if they go someplace else.
Q. Right. Now, Doctor, I'm going to have handed to you Exhibit No. 2, which I believe is your expert report.
A. Yes.
Q. And --
A. Oh, sorry.
Q. Or is it not Exhibit 2?
MR. BENTLEY: It just got flipped.
Exhibit 3 will be the report, 2 will be the reliance list.
(Exhibits 2 and 3 marked for identification.)
BY MR. ZONIES:
Q. Okay. Doctor, actually, I'm having both of those handed you, your expert report for TVT-O, which is Exhibit 3, and the reliance list that we were provided is Exhibit 2.

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Do you have those in front of you?
A. I do.
Q. Now, Exhibit 3 is your report on the TVT-O; is that correct?
A. That's correct.
Q. And when did you begin working on this report?
A. Oh, boy. Well before March, when you were here before. I would say, two or three months before March.
Q. And what you mean by that is, is your report that we discussed in your last deposition was primarily a TVT retropubic report; is that right?
A. It was a historical report on TV -- on the management of stress urinary incontinence.
Q. And what you've done for the report that's Exhibit 3 that we're talking about today is, is that you put that sort of as the baseline, and then you've made modifications to that earlier report; is that fair?
A. Yes. I would say that I beefed it up with more data and TVT-O information.
Q. Right.
A. Yes.
Q. And so the beefing up portion of drafting

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what's Exhibit 3, that occurred -- when did you start to beef it up?
A. Right after March.
(Exhibit 4 marked for identification.)
BY MR. ZONIES:
Q. So I think we have your invoices there for the after-March periods.
A. Yes, we do.
Q. Are those marked as an exhibit, Doctor?
A. Yes, Exhibit 4.
Q. Okay. So Exhibit 4, could you please --
A. Are these all of them? Yeah.
Q. Can you describe for us the first invoice that begins April 7th, 2016?
A. Right.
Q. Do you see that?
A. Yes.
Q. All right. What I'd like to do, Doctor, is just look at that first entry, which is "April 7th, 2016, two hours, review and redo reliance list for TVT report."
Do you see that entry?
A. Yes, I do.
Q. Can you describe for me, generally, what that

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work was?
A. It was to review the report, and then to see what exactly I needed to put in there and what information was lacking. Because after that initial deposition, I felt like I needed to put more in there.
And then the reliance list was just I asked to see a lot more of the documents -- or documents that you all were asking me about, both company documents as well as non-company documents.
Q. Now, at your last deposition, you had a reliance list; do you recall that?
A. I do.
Q. And subsequent to that deposition, you issued an amended reliance list.
Did you take part in creating the amended reliance list?
A. I did.
Q. And what was your objective in creating the amended reliance list?
A. To make sure I was familiar with as much of the data and the documents that are in the reliance list that I was not familiar with on the first deposition.
Q. Okay. And we actually received, from the attorneys, an amended reliance list that had removed a

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bunch of material.
Did you work on that reliance list?
A. Yes.
Q. And so, what you're looking at as Exhibit 2 there, that's actually the third reliance list for your report; is that fair?
A. Yes.
Q. So the two hours that you spent in April, was that -- it says "redo reliance list" -- was that time spent editing down your original reliance list to actually reflect what you reviewed for that first report?
A. That would have been part of it, yes.
Q. Okay. Then, in your next number of entries, it's -- who is Jordan walker?
A. He's the attorney from Butler Snow who's sitting right next to me.
MR. WALKER: He's the guy in the room right now.
And let me just remind you not to discuss any of the conversations that we've had, but you can certainly talk about the time spent --
THE WITNESS: Gotcha.
MR. WALKER: -- and that sort of thing.

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THE WITNESS: Okay.
BY MR. ZONIES:
Q. And in that, you've spent an hour with Mr. Walker. But I'm more interested in what's described there, which was, you say that hour was spent discussing Prolift report and case-specific reports; is that fair?
A. Yes.
Q. You didn't do any work on the TVT-O report in that one hour?
A. No.
Q. And then the next entry is, review your deposition in the Thelma Wright case.
That was a deposition you'd already given?
A. That's correct.
Q. And you didn't spend any time, in those three hours, working on this TVT-O report; is that fair?
A. That's correct.
Q. All right. So you can see where I'm going with this, which is I'm just trying to identify -- are there any entries on this invoice that would be time that you spent working on this TVT-O report, other than redoing your reliance list in April?
A. There's one down here, on 5/16. It says, "Complete TVT report." That was the TVT report.

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There's -- as we mentioned in the first one, there's a TVT report.
Q. So in this invoice, at least, there was reviewing and redoing your reliance list for two hours in April; and then, on May 16th, under the entry "Complete Angela Daugherty Report, complete TVT report and begin case report on Laura Morrison" --
A. Right.
Q. -- some portion of that six hours was spent on the TVT-O report we're discussing today?
A. Correct.
Q. Do you have a sense of how much time was divvied up between those three tasks?
A. No, I don't.
Q. Okay. And if you look at the next invoice --
A. Um-hmm.
Q. -- that we were provided, that starts with May 20th -- do you have that in front of you?
A. I do.
Q. And there, the first entry is "Review Cutter records."
Is that a case-specific report you were working on?
A. Yes, it is.

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Q. And the next entry is "Review Cutter records and prepare case report."

Again, that's not to do with the TVT-O report; correct?

A. No.

Q. And then you have -- let me ask it this way.

Which of the entries on this invoice would be preparation of your TVT-O report?

A. The 5/28.

Q. "5/28, 3 hours, Review Cutter, Bates, and TOT reports"?

A. That's correct.

Q. So some portion of that three hours?

A. Yes.

Q. Anything else; or is that it?

A. On this invoice, that's it.

Q. Have you issued any other invoices in this case?

A. Yes, but I haven't received anything yet.

Q. Do you know, what was the date of your report? When did you finalize it?

A. The date of my report?

Q. I actually have June 3rd.

A. Yes, June the 3rd.

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Q. So these two invoices would have captured all of the time that you spent beefing up the TVT report into a TVT-O report; is that fair?

A. It could. And then there could have been some time that I didn't invoice that I might have invoiced later, because not all my invoices go in on time. So there could have been something that I didn't invoice on this one, that related to the TOT report or TVT report, that maybe will be reflected on my next invoice.

Q. So for these two invoices, though, we know that there are three entries that you believe reflect your work on the TVT-O report --

A. That's correct.

Q. -- is that correct?

A. That's correct.

Q. And that first entry from April, for two hours, that was actually time spent working on the reliance list, not the report, itself; is that correct?

A. It was a review on the report and the reliance list. It says review and redo reliance list for TVT report.

Q. All right. And wouldn't it be consistent that that was actually on your first report, your first

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TVT report --

A. Not --

Q. -- not necessarily on the TVT-O?

A. Not necessarily, because I had to correlate the reliance list articles with some of the references that I reference in the TOT report.

Q. Okay. So -- and then we know it's some portion of the three-hour billing and some portion of a six-hour billing. So a sum total of somewhere less than 11 hours, total, reflected on these two invoices, for your work on this TVT-O report; is that fair?

A. That looks fair.

Q. Did you work on the reliance list that is in front of you as Exhibit 2?

A. Yes, I did.

Q. Do you believe that reliance list accurately reflects the things that you've reviewed and rely upon for purposes of this TVT-O report?

A. Yes.

Q. Is it your testimony that you actually have reviewed all of the documents and studies that are reflected in that reliance list, Exhibit 2?

A. I have not reviewed every one in detail. But as I look through the reliance list, there is a large

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majority of the articles and citations that I have seen either historically, in the past, or recently.

Q. Okay.

A. But I can't say I've read every single one of them, no.

Q. The last time we spoke in -- March 29th of this year, three months ago, it was your testimony that you had not reviewed any internal Ethicon documents.

Do you recall that testimony?

A. I do.

Q. And since that time, you have reviewed some Ethicon internal documents; correct?

A. Yes, I have.

Q. And do you have a sense of how many documents you've reviewed that were internal Ethicon documents?

A. No, I don't.

MR. WALKER: And, counsel, let me just interject at this moment. I don't know if you're going to ask the doctor any questions about other materials he's brought. But we did bring with us, to this deposition, approximately eight Bankers Boxes, responsive to Schedule A, containing hard copies of materials that have been provided to Dr. Karram and that he has reviewed and weighed,

too.
So I just wanted you to know that that's there. It's not every document on his reliance list. I think that, hopefully, is contained in the thumb drive I've provided counsel opposite. But I wanted you to know, we've got a number of boxes full of binders -- full of documents here.
MR. ZONIES: Mr. Walker, I'm sorry you had to bring those.
MR. WALKER: Well, better safe than sorry; right?
MR. ZONIES: I appreciate -- for what it's worth, I appreciate your effort. But having done the same myself, with eight Bankers Boxes-plus, I know what a pain it is.
MR. WALKER: Thank you. I appreciate that.
BY MR. ZONIES:
Q. So, Doctor, when we last spoke, I asked you if you had reviewed any depositions of any Ethicon employees, and you said that you had not.
Do you recall that testimony?
A. I do.
Q. And since the time of our last deposition, have you reviewed any Ethicon employees' deposition?

A. I've seen some depositions, yes.
Q. Do you know whose depositions you've seen?
A. I haven't seen depositions in full, but I've seen parts of depositions from Dennis -- or David Robinson, Marty Weisberg. And I think those are the only two depositions I've seen, or parts of their deposition.
Q. Okay. So you've seen deposition -- you've -- since March 29th of 2016, you've reviewed portions of the depositions of Marty Weisberg and portions of the depositions of David Robinson; is that fair?
A. Yes.
Q. Any others?
A. Not that I can recall right now. But I did review a lot of documents, so...
Q. And you understand a deposition and what that looks like and how that's different from internal documents; right -- correct?
A. Yes. Yes, I do.
Q. Okay. They're a lot more boring to read, depositions, especially if I took them.
Did you happen to read my deposition of Marty Weisberg?
A. No.

Q. That could be why you don't have a clear recollection of it, let's put it that way.
A. I did read my deposition that you took of me, though.
Q. Oh. How'd I do?
A. You did okay.
Q. So your reliance list and -- where is that -- Exhibit 2 is your reliance list for this TVT-O report; is that correct?
A. That's correct.
Q. And it starts with a section that is medical literature; correct?
A. Correct.
Q. If a study is not in the -- the medical literature section, you would agree, is voluminous --
A. I would agree.
Q. -- is that right?
A. I would agree.
Q. And if a study isn't reflected here in the medical literature section, does that mean you did not rely upon it?
A. No.
Q. What does it mean, if it's not in here?
A. It means that I might have read an article or

have seen an article in a journal that I just either forgot or didn't include in my list. But that doesn't mean it's -- I didn't see it.
MR. WALKER: And to add to that, Dr. Karram brought with him, to the deposition today, five or six articles from journals that I doubt are on his reliance list, because they're very recently published and I think he obtained them after his report was served. So I just wanted you to know that they're here, in case you want them marked.
MR. ZONIES: I really appreciate that. Thank you.
And why don't we go ahead and -- do you want to take a break, Jordan, on that --
THE WITNESS: Yeah. That'd be great.
MR. ZONIES: -- and just mark them real quickly on a break, and then we can talk about them?
MR. WALKER: Yeah. Can we take five?
MR. ZONIES: Yeah. Why don't we do that.
(Brief recess taken.)
BY MR. ZONIES:
Q. Doctor, we're back from break. Are you ready to go?

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A. Yes, sir.
Q. You were going through Exhibit 2, your reliance list, before we broke.
Do you recall that?
A. Yes.
Q. And we were looking at the medical literature. And it seems that you've brought some additional literature with you today, to the deposition; is that correct?
A. That's correct.
Q. And what is it that you've brought with you?
A. It's a recently published article in the Green Journal, which is the Journal of Obstetrics and Gynecology, on "Graft and mesh used in transobturator prolapse repair: a systematic review."
MR. BENTLEY: It's marked 13.
(Exhibit 13 marked for identification.)
BY MR. ZONIES:
Q. We're marking that as Exhibit 13, Doctor.
A. Right.
Q. Any other studies that you brought with you?
A. Yes. There was a viewpoint article in the Gray Journal, the American Journal of Obstetrics and Gynecology, on "Midurethral slings: evidence-based

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medicine versus the medicolegal system."
That would be you.
(Exhibit 14 marked for identification.)
MR. WALKER: And what is that marked as?
THE WITNESS: Oh, Exhibit 14.
BY MR. ZONIES:
Q. I don't know that I'm the whole system, but I certainly am part of it.
A. Yes, you are.
(Exhibit 15 marked for identification.)
A. The third would be the new AUGS position statement on mesh use and midurethral slings for stress urinary incontinence. And that would be Exhibit 15.
Q. Okay.
(Exhibit 16 marked for identification.)
A. And then Exhibit 16 is an article in the Journal of Minimally Invasive Gynecologic Surgery, "Synthetic Graft Augmentation in Vaginal Prolapse Surgery: Long-Term Objective and Subjective Outcomes."
Q. Okay. And that's --
A. That's 16. Sorry?
Q. Exhibit 16 concerns prolapse; is that correct?
A. Yes, prolapse surgery.

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And then this article came out in the Green Journal, Journal of Obstetrics and Gynecology, "Surgeon Experience and Complications of Transvaginal Prolapse Mesh." And that's Exhibit 17.
(Exhibit 17 marked for identification.)
Q. So Exhibit 17, Doctor, there's a finding in that paper that surgeon experience does not have an impact on outcomes; is that correct?
A. Come again?
Q. The paper, Exhibit 17 --
A. Yes.
Q. -- that we're just discussing, what is the conclusion in that --
A. Oh.
Q. -- paper about surgeon experience?
A. "Approximately 5 percent of women who underwent mesh-based prolapse surgery required reoperation for a mesh complication within 10 years. The risk of reoperation was lowest for surgeons performing 14 or more procedures per year."
Is that what you want?
Q. And -- yes, that's correct.
The "14 or more procedures per year" language -- how many procedures, per year, do you perform,

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Doctor?
A. Mesh procedures or sling procedures?
Q. Sling.
A. Oh, sling. I probably -- I probably do -- let me see. I can't give you the exact number. I think my estimate was 2,000 slings that I've done in my career. So if you want to extrapolate that out per month, you can probably -- it's pretty -- it might be a little more now than I did earlier in my career, but it would give you an average.
Q. Right. And, I mean, would it be fair to say you do somewhere around 100 slings per year?
A. Yes, or more.
Q. And do you know -- do you agree that a physician who does 14 or fewer slings per year -- is it your opinion that such a physician will have a higher complication rate?
A. I can't make that opinion. And that's really not -- that's an opinion more for the credentialing committee that -- at the hospital or facility that the physician works at.
Q. Okay. You started to perform sling surgeries after -- I think, when we originally spoke, after observing maybe five --

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A. And --
Q. -- sling surgeries --
A. Sorry.
Q. -- with your brother; is that right?
A. That's correct, and going to a course before that, yes, a cadaver course.
MR. WALKER: I'm sorry, counselor. I hate to interrupt. But I thought that that earlier set of questions was in regard to TVT-O.
Was your question, now, about his first time to ever use a sling?
MR. ZONIES: Thank you, Jordan, that's correct, it was that. But if I'm recalling from our last deposition, it was actually pretty much the same. And I may be wrong.
BY MR. ZONIES:
Q. So let me ask you, Doctor --
A. Yes.
Q. -- when you first started to use midurethral slings to treat stress urinary incontinence, you used the -- Ethicon's TVT retropubic device; is that correct?
A. That's correct.
Q. And if I recall correctly, your training for that was essentially to observe, scrubbing with your

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brother for five or so surgeries, and then you started to put them in yourself; is that correct?
A. That's correct.
Q. Any other studies that you brought with you today, Doctor?
A. No, that concludes the studies.
Q. Okay. I appreciate it.
MR. WALKER: That's apart from what's contained in the Bankers Boxes.
MR. ZONIES: Right.
BY MR. ZONIES:
Q. Back to Exhibit 2, your reliance list, Doctor. After medical literature, it switches over to a section entitled "Production Materials." Is that right?
A. Yes.
Q. And these are, largely, internal Ethicon documents; correct?
A. Yes.
Q. And it's your testimony, today, that between March 29th, 2016 and today, you've reviewed some portion of these documents; correct?
A. I have.
Q. There are over 400 documents in this production materials section of your reliance list --

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A. Right.
Q. -- almost 500 documents.
You didn't review all of these; correct?
A. I -- again, it depends on what you consider review. I put eyes on some. I might have read an abstract. I might have read a conclusion, like we just did on this original article or research. I have not read every single one in detail, no, but I have looked at a large number of these documents.
Q. And how did you choose which ones to look at?
A. The binders were all sent to me. And I have just as many Bankers Boxes at home as they do here. And these binders -- I don't know how you guys get all this information in these big binders. But I would just go through, and if I saw something that I thought was pertinent to this, I would at least read it or, you know, put eyes on it.
Q. And the time that you spent doing that would be time that's reflected in the two invoices that we looked at; correct?
A. That would be -- and possibly the latest invoice that I put in, as well.
Q. Your second invoice went through June 7th --
A. Right.

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Q. -- and you issued this report four days before that. So --
A. Correct.
Q. -- are you saying that there's time after June 7th --
A. There -- oh, go ahead. Sorry.
Q. No. Go ahead.
A. I was just going to say --
Q. Why don't you explain to me.
A. -- there are probably invoices from before June the 3rd, that aren't reflected on this last invoice and might be reflected on the latest invoice, is what I'm saying. You know, when you try to keep track of these, sometimes you misplace certain times. So, in going back in your records, you say, oh, on this day I did two extra hours on TVT report or worked on my reliance list and I forgot to bill for it. So those types of things.
Q. Okay. And do you know if any of that actually occurred here and will be on your invoice, or you're not sure?
A. I'm not sure. I'm just saying that there's a possibility.
Q. After the production materials on Exhibit 2,

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your reliance list --
A. Yes.
Q. -- comes a section called "Company Witness Depositions." Do you see that?
A. Yes.
Q. You did not review all of those depositions; correct?
A. I did not.
Q. You didn't even lay eyes on most of these; correct?
A. Well, let me get to them, first.
I saw part of Axel Arnaud's, a part of Piet Hinoul's. Let me see. I think I saw part of Megan Chang's, David Robinson, as we mentioned before, Charlotte Owens, Marty Weisberg.
Those are the ones that I remember seeing.
Q. So, for example, you don't recall reviewing Laura Angelini's deposition?
A. I do not.
Q. You don't recall reviewing Thomas Barbolt's deposition?
A. No.
Q. Catherine Beath?
A. Who? Which one?

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Q. Catherine Beath?
A. With a "B"?
Q. B-E --
A. Oh, Beath.
Q. -- A-T-H.
A. No. No.
Q. Scott Ciarrocca?
A. Not that I recall.
Q. Did you review Meng Chen's deposition, or some portion of that?
A. I think I did see something from her dep -- is it a her? I think it's a her.
Q. Yes, it is.
A. Yes, I think I saw something from her -- from that deposition.
Q. And you recall that because it was excellent; is that correct?
A. No, because of the funny name.
Q. Did you review James Hart's deposition?
A. No.
Q. Bridgette Hellhammer?
A. Not that I recall.
Q. Piet Hinoul?
A. Yes, I saw some of his deposition.

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Q. And Piet Hinoul has been deposed, as you can see --
A. Many times.
Q. -- three, six, eight times.
Do you know -- did you read eight different Piet Hinoul depositions?
A. No.
Q. How about Joerg Hoelste; did you read his deposition?
A. No.
Q. So it'd be fair to say you don't know what his opinions are about the TVT mesh; correct?
A. That's correct.
Q. And the same with Bridgette Hellhammer, James Hart, Scott Ciarrocca, Catherine Beath, Thomas Barbolt, Laura Angelini, you don't have any information about their thoughts on the safety and efficacy of the TVT-O device; correct?
A. Correct.
Q. Kimberly Hunsicker?
A. No.
Q. Richard Isenberg?
A. No.
Q. Scott Jones?

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A. I might have seen something from his.
Q. How about Gene Kammerer?
A. Not that I remember.
Q. So, for example, you don't know Kammerer's position on whether or not mechanically-cut mesh can degrade, fray, and rope?
A. No, I do not.
Q. Never seen the slides presented, internally at Ethicon, demonstrating that mechanically-cut mesh frays and ropes and had loose particles in the packaging; correct?
A. I don't remember seeing any slides, no.
Q. Ethicon's lawyers did not give you those slides; correct?
MR. WALKER: Object to form.
A. If they're in the multitude of boxes and folders that are in there, there are some things that I haven't looked at. So if they're in -- they're probably in there. I just haven't seen them.
Q. You did not read the deposition of Dr. Kirkemo?
A. Aaron Kirkemo?
Q. Yes.
A. Actually, I think I saw something from his,

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as well.
Q. Did you read the entire deposition, or you just saw some snippet that was provided to you by the attorneys?
A. I saw some discussion points. Yeah, it wasn't the whole deposition. No.
Q. And what do you mean when you say "discussion points"? Did somebody --
A. I mean --
Q. -- summarize depos and --
A. No, no, no. It would be directly from a his deposition. It would just be -- but it wouldn't be the whole deposition; it would just be a transcript from it.
Q. Do you recall Dr. Kirkemo's deposition, where he's discussing the TVT Abbrevo and where he opines, in his deposition, that the Abbrevo is a safer, more effective alternative to the TVT-O device?
MR. WALKER: Object to form.
A. I don't remember that.
Q. Is that an opinion with which you would agree?
A. Not necessarily.
Q. Daniel Lamont, do you recall reading his deposition?

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A. No.
Q. Bryan Lisa?
A. No.
Q. Sheri McCoy?
A. No.
Q. Sean O'Bryan?
A. No.
Q. You said you do recall reading some of Dr. Owens' deposition?
A. Yeah, I -- something. Again, that name rings a bell, yes.
Q. So do you recall that during Dr. Owens' deposition, she testified that there were a great number of reports of permanent nerve injury, groin and leg pain associated with the TVT-O device?
MR. WALKER: Object to form.
A. No, I don't remember that.
Q. You don't recall reading that portion of the deposition?
A. No.
Q. But some portion of the deposition was provided to you to read, just not that portion?
A. The name -- you know, it might have even been an internal document from Charlotte Owens. I'm just

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telling you the names that sound -- that I can recall seeing something from. Whether it was, for sure, the depositions were -- I know some things from David Robinson and some things from Marty Weisberg and the other ones that I've mentioned. But I can't say for sure that I saw it was directly from her deposition.
Q. Okay. So if we were to amend this reliance list to accurately reflect what you actually reviewed and relied upon, we could take out a great number of these depositions; is that correct?
A. Yes, I would say so.
Q. The next section of your reliance materials is called "Other Materials" and talks about "Publicly Available" --
A. Yes.
Q. -- right?
A. Yes.
Q. What does that mean to you, "publicly available"?
A. That means that anybody can find it through multiple different avenues, Internet, online, journals, scientific organizations, et cetera.
Q. And did you actually find all of these documents yourself, under the publicly available

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documents, or were they provided to you by Ethicon's counsel?
A. No, I have these.
There is ACOG Bulletins. I'm a member of ACOG, so I have all the ACOG Bulletins. There's ACOG Committee Opinions. I'm well aware of the FDA notifications. I personally pulled that off. The NIH Interventional Procedure Overview, I have that. I'm a member of IUGA. So the IUGA 2004 ICS I have. And I pulled off the 2008 FDA Health Notification. The Executive's Committee Statement from the FDA, I have. The AUA Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse, I have. The IUGA Pelvic Organ Prolapse Guide for Women, I actually have that and use that in my office. The ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery, I have that. And we actually have to use that when we teach our fellows, as they prepare for their board examinations. The update --
Q. One of the documents --
A. -- the updated AUA SUA Guidelines, I have that. Frequently Asked ACOG Questions, I have that. The AUGS Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders, I have that, and I

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pulled that up. AUA Position Statement, I have. The UGSA Position Statement, I have. The NICE Guidelines, I have. The AUGS SUFU Midurethral Sling Position Statement, I have. The IUGA Position Statement. The AUGS SUFU Frequently Asked Questions, I have. ACOG Practice Bulletin.

Yes, I have all these, and I pulled these -- if I don't have them, I pulled them myself.

Q. Okay. And so, to be clear, Doctor, in March of 2016, when I asked you if you had read any internal documents, your testimony was that you hadn't by that time; correct?

A. That's correct. But these aren't internal documents that I'm listing here.

Q. No, I understand.

A. Okay. Yes, I had not -- I had not read any. Sorry.

Q. And in your Exhibit 2, your reliance list for this report three months later, there are 493 new internal documents listed.

A. That's correct.

Q. Is it your testimony that you reviewed and relied upon all of those 493 documents, in the time between March 29th and today?

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MR. WALKER: Object to form.

A. I did not review them all, but I looked at a large number of them which I hadn't looked at before.

Q. And with regard to the deposition testimony listed in your reliance materials, I think we've established that you did not review a great number of those depositions, although they're on your reliance materials; correct?

A. I did --

MR. WALKER: Object to form.

A. Oh. I did not review the entire depositions, but I did see excerpts of some of them.

Q. The materials in your reliance list, as you pointed out earlier, cover both midurethral slings and POP prolapse materials; is that correct?

A. That's correct.

Q. And your reliance list is the same for both your Prolift report, that you're going to discuss later today, and your TVT-O report; correct?

A. Yes.

Q. So the same would apply to the Prolift report and the reliance materials for that; meaning, the 493 internal documents and the 73 company witness depositions, you would have reviewed all of those if --

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whatever portion of those you reviewed, that review would have been done since March 29th; correct?

A. That's correct.

Q. If I could get you -- turning to your report, which is Exhibit 3, Doctor.

A. Okay. Got it.

Q. If you could turn to page 11 of your report.

A. Yes. Okay.

Q. Got that?

A. Yes.

Q. Doctor, do you have an opinion, within a reasonable degree of medical certainty, about whether there is more groin and thigh pain associated with the TVT-O, as compared to the Monarc?

A. What was your question again?

Q. Comparing the outside-in approach to the inside-out approach of TVT-O --

A. Right.

Q. -- in your opinion, which of those procedures, if either, inflicts more leg and groin pain on a patient?

MR. WALKER: Object to form.

A. I would say that the risk is equal in both sides.

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Q. That the risk for groin, inner thigh, or leg pain is equal, when you compare inside-out TVT-O to outside-in TOT; is that your testimony?

A. Yes.

Q. So, in your report on page 11, you say, about halfway through that first paragraph --

A. Okay.

Q. -- there's a sentence that begins with, "With the inside-out TVT-O..." Do you see that sentence?

A. Yeah, I got it, "With" -- yes.

Q. Okay. So you wrote in your report, "With the inside-out TVT-O, the chance of experiencing groin, inner thigh, or leg pain is much less than the outside-in approach."

A. Right.

Q. That's what is in your report; correct?

A. Right, right. And I think --

Q. You don't --

A. You were asking my opinion. I think there's data to support this.

But my opinion is, if they're put in correctly, it's equal. But I think there is some literature out there that will compare the two, based on multiple different surgeons or cites, where they have

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shown -- and I don't know if it was statistically significant or not -- that the outside-in might have a higher incidence of groin pain than the inside-out.

Q. So what I'd like to know, Doctor, is, would you revise this opinion to say, with the inside-out TVT-O there is some literature that reflects -- or how would you modify that sentence --

A. I would say --

MR. WALKER: Object to form.

A. Oh. I would say any transobturator sling has the risk of inner thigh pain, groin pain, or leg pain.

Q. So to the extent that this sentence implies or states that the TVT-O exhibits less chance of experiencing groin, inner thigh, or leg pain than a TOT device, you would strike the sentence?

MR. WALKER: Object to form.

A. No. I would say there's data to support that the outside-in has a higher risk, but all TOTs have a risk of that.

Q. And what data is it that you would rely upon for that?

A. I can't quote you the articles. But I think there have been some -- they weren't randomized trial, but just some comparative trials at certain institutions

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that did outside-in and inside-out and followed them for a certain length of time. And they showed that there was a little higher incidence of -- or a higher incidence. And I can also base that on my experience, as well.

Q. So, Doctor, I'm going to ask it this way, which is, it your opinion, within a reasonable degree of medical certainty, that with the inside-out TVT-O, the chance of experiencing groin, inner thigh, or leg pain is much less than the outside-in approach?

A. If --

Q. That is your opinion --

A. Yes, if --

Q. -- within a --

A. If performed correctly, yes.

Q. And as we sit here today, you can't identify any literature that supports that opinion?

A. I don't have that off the top of my head, no.

(Exhibit 18 marked for identification.)

BY MR. ZONIES:

Q. Are you aware that in the Cochrane Review -- Ford's Cochrane Review in 2015, comparing TVT-O and TOT pain issues, that there was a similar nonstatistically significant similarity between the two?

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A. You know, I don't have that Cochrane Review -- I think I do -- hang on. But that's -- you know -- let me see. That sounds familiar, yes. Here it is.

Q. And, in fact, it showed that TVT-O was nonstatistically significantly higher risk for inner thigh and groin pain; correct?

A. Well, I'm looking at that right now. Is this the -- you talking about the 2015?

Q. 2015.

A. Yeah. Okay. Let' see.

Q. It's on page 227, Doctor, if you have Cochrane in front of you.

A. I do, but it's not 227.

MR. ZONIES: Greg, do you have our full version of Cochrane?

MR. WALKER: I mean, I think you got the full version.

THE WITNESS: Yeah, I do. I'm just trying to --

MR. WALKER: And I've got a "227" --

THE WITNESS: Oh, it does? Okay.

MR. WALKER: -- on mine.

THE WITNESS: Yeah, maybe. 227. Yes. Okay.

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We're getting there. Okay.

BY MR. ZONIES:

Q. Now, Doctor --

A. Obturator medial to lateral approach versus obturator lateral to medial approach, outcome 9 -- 19. Okay?

Q. Yes. You're at --

A. Yes.

Q. -- Analysis 3.19; correct?

A. Correct.

Q. And in that analysis, in this Cochrane Review --

A. Um-hmm.

Q. You rely upon the Cochrane Review in the rest of your report; correct?

A. I do.

Q. You believe the Cochrane Review to be sound scientific literature; correct?

A. I do.

Q. And in this table on page 227 of the Cochrane Review, it actually shows that when looking at groin/thigh pain, it favors the outside-in approach over the TVT-O; correct?

A. No, because it didn't reach statistical

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significance.
Q. So they're statistically the same; correct?
A. Correct.
Q. And isn't that really your opinion? Because that was the first opinion you've expressed --
A. Yes.
Q. -- which is --
A. Yes.
Q. -- as comparing the TVT-O and outside-in, it's your belief, to a reasonable degree of medical certainty, that they are equal on experiencing groin, inner thigh, or leg pain; correct?
A. Well --
MR. WALKER: Object to form.
A. -- I guess, in my original report -- and I still stand by this -- some of that report was based on my education, training and experience. And based on my experience either scrubbing with other doctors or watching other doctors or seeing patients from other doctors, I see a higher risk of inner thigh pain and groin pain with the outside-in than the inside-out. So that was --
Q. So --
A. -- that was part of my opinion when I put

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that statement in my report, my education, experience and training.
Q. When you're consenting your patients, Doctor --
A. Yes.
Q. -- do you tell them that it's your belief that the outside-in has a higher incidence of groin, inner thigh, or leg pain --
A. Absolutely. Absolutely.
Q. That's helped to shorten a line of questioning, Doctor.
A. What's that?
Q. That's how you shorten a line of questioning.
A. What, say "absolutely"?
Q. Doctor, I notice, in your report, that you did not cite to or discuss the Teo study, T-E-O.
Do you know of that study?
A. I know of it. It sounds familiar, but I can't recite exactly the -- what -- word verbatim, but I have seen it or heard of it.
Q. And the Teo study was comparing TVT retropubic to TVT obturator, and the study had to be stopped early because of the high incidence of leg and groin pain associated with the use of the TVT-O.

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Do you recall that?
A. No. Do you have -- if you have the study, I'll be happy to look at it.
MR. ZONIES: Greg, do you have Teo?
MR. BENTLEY: Yes, it will be Exhibit 5.
THE WITNESS: Okay.
MR. BENTLEY: And just for the record, we put the Cochrane 4/20/15 marked as Exhibit 18.
MR. ZONIES: Thank you.
(Exhibit 5 marked for identification.)
BY MR. ZONIES:
Q. So if you're looking at the -- do you have the Teo study in front of you?
A. I --
Q. Doctor --
A. I do.
Q. -- Exhibit 5?
A. I do.
Q. And if you look at the Teo paper, in the results section in the abstract, on the front --
A. Um-hmm.
Q. -- are you with me --
A. Yes.
Q. -- "A total of 127 women were recruited. The

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study was stopped early due to excess leg pain in the tension-free vaginal tape obturator group."
Is that what the results were of that study?
A. That's what it says here, yes.
Q. And this is not a study that you discuss or even cite to in your report; correct?
A. I don't think I did.
Q. Why not?
A. Because there is a totally large abundance of information in peer-review literature, meta-analyses, randomized control trials that does not show the same results. So this is just one study. And, quite honestly, it looks -- you know, I don't know -- did it meet with the p-value? Did it meet statistical significance? You have to look at -- you have to look at who was put -- performing the surgery, how many TVTs or TOTs they have done prior to performing the study. There's a lot of variables in here and confounding variables that really influence the results, to just say right out front that this is a study that you quote that says outside-in -- inside-out has more leg pain than outside-in. So that's why I didn't include it.
Q. One of the reasons -- one of the concerns you had was whether or not it reached significance?

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A. Yes.
Q. If you look down in that same results section --
A. Yeah.
Q. -- it says, "More women complained of leg pain after receiving a tension-free vaginal tape obturator or" --
A. Right.
Q. -- "TVT-O." And that's at 26 percent, more than a quarter, of the women experienced pain compared to 1.7 percent of TVT retropubic with a p-value of .0001?
A. Got it.
Q. That's what we would say is very statistically significant?
A. That is statistically significant, in this population, with these surgeons, yes.
Q. This was a study you chose not to discuss; correct?
MR. WALKER: Object to form.
A. I think the overwhelming majority of good scientific data disputes this result.
Q. So why didn't you discuss it and say that? That's my concern, Doctor, is, you know, we had to find

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this and we have to present it to you.
In your report, were you attempting to be objective in your analysis?
MR. WALKER: Object to form.
A. I'm absolutely being objective. But, you know, I can only rely on peer-review meta-analyses. I can rely on randomized control trials. I can rely on United States data that is proposed in multiple different journals. I can rely on my experience, in talking to other physicians and surgeons, and watching other physicians and surgeons perform this, and looking at the society results of these issues, and all the experts in the field, and I come up with a conclusion.
So this one --
Q. Would you --
A. -- this article really didn't influence my decision as to that statement.
Q. Do you know the Journal of Urology?
A. I sure do.
Q. Do you receive the Journal of Urology?
A. I do not.
Q. Is it a peer-reviewed journal?
A. It is.
Q. Do you see, on the first page, where it's

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disclosing the financial interests of the authors?
A. I do.
Q. It says, "Financial interest for Paul Moran: Financial interest and/or relationship with Astellas..." That's a mesh manufacturer; correct?
A. No, I don't think so.
Q. Gynecare, that's Ethicon; correct?
A. That's correct.
Q. American Medical Systems, they make the Monarc; correct?
A. Correct.
Q. Bard and Boston Scientific are both mesh manufacturers, as well; correct?
A. That's correct.
Q. And the next physician, Christopher Mayne, he has a financial interest and/or other relationship with Gynecare and American Medical Systems; correct?
A. Correct.
Q. These are well-versed physicians in mesh; correct?
A. They are.
Q. Discussing pain, Doctor, do you agree or disagree with the following statement: Inside-out slings may result in a little more thigh pain if the

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surgeon passes the needle too far lateral in the thigh muscle?
MR. WALKER: Object to form.
A. Without quantifying how far lateral, I think, as a general statement, the farther out you go past the ischiopubic ramus, the higher the incidence of pain, groin pain, or other complications.
Q. And is it more likely to go too far lateral using the TVT-O, as compared to the TOT?
A. No, it's less likely.
Q. If you had to quantify the percentage of patients, based upon the literature or your experience, who experience leg, groin, or thigh pain associated with the use of the TVT-O, how would you quantify that, percentagewise?
A. In my patient population?
Q. We can start there, if you'd like.
A. I mean -- so I didn't quite catch your question. How do I quantify it? In other words, do -- oh, go ahead.
Q. In the Teo study --
A. Yes.
Q. -- almost a quarter of the patients had leg or groin pain.

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A. Um-hmm.
Q. Do you find, in your patient population, that a quarter of your patients have leg, groin, or thigh pain?
A. No, not even close.
Q. How about 15 percent?
A. No.
Q. You discuss, on page 14 of your report, the Tommaselli study --
A. Yes.
Q. -- is that right?
A. Yes.
Q. And in the Tommaselli study, there was also a finding of increased pain, comparing the TVT-O to mini slings; correct?
A. What -- again, what are you trying -- on page 14, is that what you're talking about?
Q. Well, if we turn to page 14 of your report --
A. Right, that's what I'm saying.
Q. Yes.
A. Okay.
Q. Then, where you're discussing the groin and thigh pain -- all right. Do you have the Tommaselli study with you? Or we can give it to you, I think.

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A. I'm sure I have it someplace. But let me see.
MR. WALKER: He has it. But it would be helpful if you could provide it, just given how his materials are.
MR. ZONIES: Okay.
MR. WALKER: Organized. Thank you.
MR. BENTLEY: So I'm handing the witness Tommaselli 2015, which is marked as Exhibit 8.
(Exhibit 8 marked for identification.)
A. Okay, I have it.
BY MR. ZONIES:
Q. You rely upon this paper in your report; correct?
A. I do.
Q. And if you look in the results section, the last sentence in the results section says, "Pain-related complications were more common with transobturator midurethral slings than with minimally invasive tapes, with an odds ratio that's statistically significant from 8.75." Correct?
A. I'm trying to find it in the results section. Okay. Here you go.
Q. It's in the abstract.

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A. Yes, I got it.
Q. So do you see -- and do you agree with the conclusion in Tommaselli, a paper you rely upon, that pain-related complications were more common with transobturator midurethral slings than with minimally invasive tapes, with an odds ratio of 8.75 statistically significant confidence interval, going all the way up to 57?
A. I'm looking at this and I'm trying to quantify what he meant -- what they meant by "minimally invasive slings."
Are they talking about single-incision slings?
Q. They are. I can help you with that.
A. Okay.
Q. I had to do the same thing, myself.
A. Okay. Okay. And so pain-related complications are more common with transobturator than -- yes, I would agree with that.
But a mini sling -- a mini sling is not the same as a transobturator. It doesn't have the same results. You can't use it in the same patient population. So it's really comparing apples to oranges.
Q. And if you turn, in Tommaselli, to Figure 6,

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please --
A. Okay.
Q. -- which is -- it doesn't have page numbers. I'm sorry. It's one, two, three, four, five -- but I'm double-sided -- I don't know if you are -- five pages in.
A. Figure 6? Yeah, I got it.
Q. Yeah. So Figure 6 is actually looking at the complications in the studies evaluating long-term and medium-term outcomes, and compares retropubic and transobturator; correct?
A. Correct.
Q. And the top line in that graph is reflecting that pain, in the transobturator approach, is more than doubled compared to the retropubic approach, and it's also statistically significant; correct?
A. Yes.
Q. So you would agree with me, Doctor, that Tommaselli reflects that the transobturator approach is associated with more pain than both mini slings and the TVT retropubic; correct?
A. That's correct.
Q. And that's actually your opinion, as well, in this case; correct?

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A. Yes, that's correct, even though we didn't -- we didn't really do an analysis of the mini slings. But in my experience, yes, that's correct.
Q. Doctor, I'd like you to continue in your report, if you would, to page 14.
A. Okay. Okay.
Q. With me?
A. Yes.
Q. Okay. On page 14, down at the bottom of the page, you have a heading called "Data Comparing TVT and TVT-O (TOMUS Trial)." Correct?
A. Correct.
Q. And is that what is supposed to be reflected in the slides on page 15?
A. That's correct.
Q. Now, the slides on page 15 are not from the TOMUS trial, are they?
A. If I'm not mistaken, I think they are.
Q. Where did the slides on page 15 come from?
A. I think they came from the TOMUS Trial. I'm pretty --
Q. Did you pull these out yourself?
A. Yes. Yes, I did.
Q. You have these slides on your computer?

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A. I have them in PowerPoints, yes.
Q. On your computer?
A. On my computer, in PowerPoint slides that we present when we're giving talks on SUI.
Q. So, Doctor, you recall when we first met and we discussed some of the slides that were in your original report?
A. Yes.
Q. Do you remember that?
A. Yes.
Q. And, at that time, you said that you had those slides on your computer. Do you recall that?
A. Yes.
Q. Has anybody asked you to provide those slides to us?
A. I think they're in the -- in the document that you asked, yes.
Q. Has anybody asked you to provide the entire PowerPoint to us that's on your computer?
A. No.
Q. Never?
A. Well, I think you asked me about some PowerPoints and some discussions and slides that I took from other presentations, such as the AUGS review course

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for female pelvic medicine and reconstructive surgery, and I said those are publicly available on the Internet, just like all the these other articles, and you can access them just as I can.
Q. Well, did -- so the two slides we're looking -- do you know a Dr. Paraiso?
A. Paraiso? Yes, I do.
Q. Have you ever spoken with Dr. Paraiso?
A. Absolutely. She's a friend of mine, and she was a resident under me in training.
Q. Has she ever provided to you her slide deck that she uses to give talks on mesh?
A. I have been at her talks. And she has allowed anybody that she gives those talks to to use her slides, yes.
Q. Do you recognize these two slides are from her presentation?
A. I do not.
Q. Okay. And the slides in your original report that are no longer in this report, those were also from that same presentation; correct?
A. That might have been, yes.
Q. So, if you -- it's your testimony that your -- these two slides reflect results from the TOMUS

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Trial, T-O-M-U-S; correct?
A. I -- yes, that's what -- I'm sure -- pretty sure, this is from the TOMUS Trial.
Q. You see on that first slide, Doctor, where it says "From Barber 2006"?
A. Correct.
Q. Have you ever read the Barber study?
A. I've looked at it, yes.
Q. The Barber study is not listed in your reliance materials. And I suspect that's because the Barber study was actually not on the TVT-O, it was on the Monarc.
A. Okay.
Q. Is that correct?
A. I'm not sure.
Q. And, Doctor, I'll represent to you that these two slides are actually, as they state, from the Barber Study 2006, that had nothing to do -- had no TVT-O devices in the study.
A. Okay.
Q. All right? So my question is, is why are these in your paper, if they have nothing to do with TVT-O?
A. Because I was under the impression that they

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were from the TOMUS Trial.
Q. If they're not from the TOMUS Trial, they should be deleted from your report; correct?
A. I would say, yes, other than for general knowledge and comparing transobturator procedures to trans -- or to retropubic procedures. Because just as you referenced the TOMUS study, comparing it to mini slings, I think this is important. Even though it isn't from the TOMUS Trial, it does show that -- the differences between retropubic and transobturator.
Q. All right. Now, Doctor, the Paraiso slide deck --
A. Um-hmm.
Q. -- that these slides came from, do you have that slide deck on your computer?
A. I probably do, yes.
Q. And is it your testimony that since March 29th, 2016, Ethicon's lawyers did not ask you to provide them with that PowerPoint?
MR. WALKER: Object to form.
A. Yes, they didn't ask me for it.
Q. Had they asked you for it, would you have provided it to them?
A. Yes.

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MR. ZONIES: How much time are we in?
THE REPORTER: One moment, please.
MR. ZONIES: Why don't we go ahead and go off the record.
(Brief recess taken.)
BY MR. ZONIES:
Q. Doctor, we're back from a randomized break. Are you ready to go?
A. I am.
Q. I've just got a few more questions.
I'd like you to turn to page 16 of your report, please.
A. Okay.
Q. On page 16 of your report, you discuss -- it's the one, two, three, fourth paragraph down, where you're discussing subjective and objective cure rates using TVT-O; correct?
A. One, two, three -- the Cochrane Library published meta-analysis?
Q. Yes.
A. Okay. Yes.
Q. And you also discuss, there, the TOMUS Trial; correct?
A. Correct.

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Q. So in those two studies, they report short-term cure rates between 73 percent and 82 percent in the Cochrane, according to your report; correct?
A. Right.
Q. And then, in TOMUS, you describe it as showing subjective and objective cure rates of 62 percent and 78 percent, respectively; correct?
A. Correct.
Q. Now, you also have a next sentence there, which is two prospective cohort studies reporting 7-year and 11-year follow-up reported subjective cure rates of 85 and 77 percent, respectively.
I think you would agree with me that that's discussing TVT results, because it's 7-year and 11-year data, primarily the Nilsson studies; correct?
A. Correct. Correct.
Q. All right. So focusing on the Cochrane Library results and the TOMUS results, do you believe those results to be a fair reflection of the cure rates associated with a TVT obturator device?
A. Yes.
Q. So would your testimony be that the cure rates associated with the TVT obturator device are somewhere between 62 and 82 percent?

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A. Yes.
Q. Would you agree, Doctor, that it would be misleading to ascribe a cure rate to the TVT-O of 90 percent or higher?
MR. WALKER: Object to form.
A. Again, I'd have to look at the report and how they came up with that number, to just make a comment --
Q. Right.
A. -- across the board.
Q. So if someone were presenting you a patient, for example, the cure rate associated with the TVT-O device, and they were presenting it as 90 percent or higher cure rate, without discussing any lower cure rates, such as shown in the Cochrane Library study or the TOMUS study, don't you think that would be misleading?
MR. WALKER: Object to form.
A. It's hard to say. But when you're -- a lot of times, when you're consenting a patient or talking to a patient about procedures, it's always -- or usually incorporates -- and I do this -- my personal experience. So if a surgeon, you know, knows these results from the TOMUS Trial and the Cochrane Review, but in his hands -- his or her hands, he has a 90 percent cure rate, then I

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wouldn't say it's misleading.
So a lot of that discussion has to do with the discussion that the surgeon and the patient have together.
Q. Right. And I'm talking about -- let's -- I'd like you to assume for a second, Doctor, that there's a sales piece from Ethicon discussing the TVT-O; and the only results that they show, cure rates associated with the TVT-O, are 90 percent and higher.
Isn't that his leading, based on your experience and on these studies?
MR. WALKER: Object to form.
A. I'm not aware of that document. But I would like to look at that document and see the context of the document and how it was presented in the context of that number.
Q. Do you understand the concept of fair and balanced, Doctor?
A. I do. Absolutely I do.
Q. Do you think that that's important, the concept of fair and balanced? In fact, when you're discussing mesh slings with your patients, you attempt to be fair and balanced; correct?
MR. WALKER: Object to form.

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A. Yes, I do.
Q. Why?
A. Why?
MR. WALKER: Object to form.
A. Because that's the way I practice medicine.
Q. That's the right way to practice medicine, isn't it?
MR. WALKER: Object to form.
A. It's a matter of opinion. In my opinion, that's the way I practice medicine.
Q. So if -- you would not say to your patients that, overall, the TVT-O device demonstrates a 90-plus percent cure rate? You wouldn't say that to your patients without discussing other studies showing lower cure rates; correct?
A. I would tell her that --
MR. WALKER: Object to form.
A. -- in my hands, I can -- if that's what I was going to say, that in my hands, if that was the correct number, I would say yes. I would say, in my hands, with this procedure, in a patient as yourself, with your problem and your stress incontinence and the way we've evaluated you and worked you up, I think, in my hands, with a transobturator, TVT-O, that we could achieve a

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90 percent success rate. I wouldn't have any problems with that.
Q. And what would you say about, however, the scientific literature shows what?
A. I would mention that. I would say there is data in the scientific literature that will contradict what I'm telling you that my experience is with my patients in this situation.
Q. That's because you're attempting to be fair and balanced; correct?
MR. WALKER: Object to form.
A. I am fair and balanced.
Q. You're not attempting; you are fair and balanced?
A. I am.
Q. And you certainly would not tell your patients that, across the board, TVT-O has a 90 percent cure rate, to try to sell them the TVT-O; right?
MR. WALKER: Object to form.
A. I wouldn't, certainly, tell anybody any absolute certainty on any result.
Q. Wouldn't tell your patients that there's a 90 percent cure rate across the board, with the use of the TVT-O; correct?

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A. I think "across the board" is misleading. I could say, in the hands of some surgeons, there is a 90 percent cure rate, but that doesn't mean that every patient that has your procedure is going to have a 90 percent cure rate.
So you can't say anything across the board.
Q. That would be misleading; correct?
A. If you say it "across the board"?
MR. WALKER: Object to form.
A. Again, that would be the situation. I wouldn't say it's misleading; I would say there's a reason why there -- whoever's mentioning this is telling them and giving them that outcome.
Q. So I guess my question, Dr. Karram, is, if you were speaking to a room full of surgeons and talking about the -- not your personal experience, but the cure rate that's associated with use of the TVT-O device, would you ever tell those doctors that cure rate for the TVT-O device is 90 percent?
MR. WALKER: Object to form.
A. I wouldn't tell them the cure rate of any procedure. I would give them the information, talk about the surgical procedure, how to implant the sling correctly, how to identify the correct patient

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population for the procedure; and then I would give them the articles and the scientific data to support the results, and let them come up with a percentage. I wouldn't give them a percentage.

Q. Because you wouldn't be comfortable giving them a percentage, why?

A. Well, in my hands. It would have to be in their hands. Again, you said not in my hands. I could say, under certain circumstances, in my hands, I wouldn't have any problem saying it's 90 percent in my population, in my experience, with my patients. But you asked me not to say that. So I didn't. I just said, in general.

Q. So it wouldn't be appropriate to say it in general; correct?

MR. WALKER: Object to form.

A. I wouldn't.

Q. We were discussing, earlier, the use of the TVT-O and some limitations, in your opinion, on its use in patients with ISD; correct?

A. Yes.

Q. If you were to use a TVT-O in a patient with ISD, is the technique that you would use different than the technique that is laid out in the IFU?

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A. No.

Q. Doctor, if you could turn to the portion of your report that discusses laser-cut mesh, which I believe is page 29.

A. 29?

Q. Yes.

A. Got it.

Q. You say that "There is not a clinically significant difference between mesh that is cut mechanically or by a laser."

Is that your opinion?

A. That's my opinion, yes.

Q. Okay. And my question, Doctor, is, is what scientific basis do you have for that opinion?

A. Exactly -- tell me again where you're looking at this on page 28.

MR. WALKER: No, 29.

Q. Page 29.

A. Oh, 29. Okay.

Q. Sorry about that.

A. That's all right. Okay, here we go.

MR. WALKER: No, there you go.

A. Okay.

MR. WALKER: Could you ask that question again, just to get him reoriented?

A. Um-hmm.

Q. Sure. Doctor, page 29 of your report, you're discussing laser and mechanically-cut mesh; correct?

A. That's correct.

Q. And your opinion is that there's not a clinically significant difference between mesh that is cut mechanically or by a laser. Is that your opinion?

A. That's correct.

Q. And we've already established that you haven't seen or read Gene Kammerer's deposition testimony or the slides that he produced, internally, showing a difference between laser-cut or mechanically-cut mesh; correct?

A. I have not seen those slides, yes.

Q. So I suppose my question, then, Doctor, is, is what is your scientific basis for your conclusion that there's no clinically significant difference between laser-cut and mechanically-cut mesh?

A. I would say, my training and my experience.

Q. Okay. And you would agree with me, Doctor, that there's no published paper that tests laser-cut versus mechanically-cut mesh for outcomes, safety, and efficacy; correct?

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A. I'm not aware of any, no.

Q. And you would agree with me that you list, there, an ETH.MESH document at the end of that paragraph. Do you see that?

A. Yes.

Q. And do you know what that ETH.MESH document is?

A. I can probably pull it up. But if you have it --

Q. Especially, the "Clinical Expert Report for Laser Cut Mesh."

Do you recall ever actually reviewing that?

A. I think so, yes.

Q. And...

MR. WALKER: And do you have a copy of that for him?

MR. ZONIES: I'm not going to go into detail on it. I'm actually not going to ask another question about it.

BY MR. ZONIES:

Q. Doctor, when you are using a TVT-O device, or when you did use them historically, were you using the mechanically-cut or the laser-cut mesh?

A. I've used both.

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Q. How do you know that?
A. Because it would be, I'm pretty sure, on the device, on the box -- the actual boxed device.
Q. And did you have a preference for mechanically-cut versus laser-cut?
A. Absolutely not.
Q. Did you -- when you're currently ordering TVT-O devices right now, are you using laser-cut or mechanically-cut TVT-O?
A. Actually, I'm just asking for whatever they have in stock to send over. It doesn't matter to me one way or the other.
Q. And are you aware of whether the TVT Abbrevo is laser-cut or mechanically-cut?
A. I think it's mechanically-cut, if I'm not mistaken.
Q. And is the fact that the TVT Abbrevo, in your opinion, is mechanically-cut -- is that part of the evidence that you use in reaching your opinion that there's no clinically significant difference between mechanically-cut and laser-cut?
MR. WALKER: Object to form.
A. No.
Q. It's not part of the evidence base on which

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you have that opinion?
A. No.
MR. ZONIES: Okay. I think I'm finished, Doctor. Why don't you give me just a second to make sure.
THE WITNESS: Okay.
MR. ZONIES: Okay, Doctor. Thank you very much for your time. I appreciate it.
THE WITNESS: Nice. You, too.
MR. WALKER: All right, I do have some follow-up questions.
I think what we're going to do is just extract documents from this binder and we'll mark them as exhibits.
And, for your benefit, the binder I'm referring to is just the one he has in front of him that has his TVT-O report with the supplemental materials as attachments that he cites in that report.
(Exhibit 19 marked for identification.)
EXAMINATION
BY MR. WALKER:
Q. Okay. Doctor, I'm handing you what I've marked as Exhibit 19, which is a document you cite in

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your report entitled "Clinical Expert Report (for) Laser Cut Mesh." Do you see that?
A. Yes, I do.
Q. And do you recall reviewing this document when you prepared your report?
A. Yes.
Q. And, Doctor, what is the date of this document pertaining to laser-cut mesh?
A. March 2016 -- or 2006. I'm sorry.
Q. I was going to say, we might have a problem.
A. 2006.
Q. So this is a 2006 document; correct?
A. That's correct.
Q. And would you turn to the back -- the last page of this document? And can you tell us what was the conclusion, on the part of Ethicon, regarding laser-cut and mechanically-cut mesh?
A. "The physical properties that might affect clinical performance are essentially the same. It is not anticipated that there will be any clinical differences in the devices that utilize laser-cut mesh. Clinical data is not necessary to establish the safety and efficacy of devices affected by these changes."
Q. And, Doctor, this is an internal company

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document; correct?
A. That's correct.
Q. And you reviewed a number of internal company documents, in formulating your opinion; is that correct?
A. I did.
Q. And you also reviewed medical literature; is that correct?
A. That's correct.
Q. And, Doctor, on the spectrum of -- if you were going to rack and stack what we would call high-level evidence, where do internal company documents fall with respect to peer-reviewed medical literature?
A. At the bottom.
Q. Now, Doctor, referencing back to this document, we see this March 2006 date; correct?
A. That's correct.
Q. And this document was assessing laser-cut mesh pending its introduction to market; is that correct?
A. That's correct.
Q. And, Doctor, I believe we established, earlier in this deposition, that TVT-O was introduced on the market sometime around 2003.
Do you recall that testimony?

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A. Yes.
Q. Doctor, was there peer-reviewed medical literature published on TVT-O prior to 2006 and 2007?
A. I think there was, yes.
Q. And, Doctor, that is literature that you have reviewed in the course of your career and in preparation of your opinions in this case; correct?
A. That's correct.
Q. And, Doctor, have you also reviewed peer-reviewed medical literature that studied TVT-O post 2006 or 2007?
A. I have.
Q. And are you aware of any difference in terms of safety or efficacy, as reflected in that literature, when it comes to TVT-O, whether it's before 2006 or after 2006?
A. No, I haven't.
MR. ZONIES: Object to the form.
Q. Doctor, you brought with you today a number of different articles and a position statement that were previously marked. Do you remember that?
A. Yes.
Q. I'm going to hand you -- and if you can --
A. Sure.

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Q. -- indulge looking beside me, since I only have this one copy.
A. Yep, no problem.
Q. I am handing you what was previously marked as Exhibit 15.
Can you identify this document?
A. Yes. This is the new updated AUGS SUFU position statement on midurethral slings for stress urinary incontinence.
Q. And when AUGS and SUFU are talking about midurethral slings, does that include TVT-O?
A. It does.
Q. Doctor, you said that this was recent. How recent is this new position statement?
A. 2016. I think it just came out, because I just pulled it off -- or it was just sent to me as an AUGS member. So I think it was 2016.
Q. Did you find this position statement significant, in terms of your opinions regarding TVT-O?
A. Yes, I do.
Q. And why do you find this position statement significant?
A. Well, because AUGS and SUFU and all the other societies that have endorsed this position statement all

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conclude in their opinions that the midurethral sling, synthetic, is a safe procedure and an effective procedure in the use of stress urinary incontinence and that we should continue using it.
Q. And why is it significant to you, in the formation of your opinions, that a professional society would endorse the use of a midurethral sling like TVT-O?
A. Because all these professional societies and their members are experts in the field, and they have utilized these procedures and they have reviewed the literature and they come up with conclusions and they are very important societies to back your conclusions.
Q. In fairness, Doctor, is it your understanding that this position statement was released after you served your report in Wave 2?
A. It was.
Q. And prior to this position statement, were there other position statements that had been released prior to June 3rd of 2016?
A. Yes.
MR. ZONIES: Object to the form.
Q. Are the recommendations and conclusions in this position statement consistent with those that you reviewed and relied on when you were forming your

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opinions, in this case, regarding TVT-O?
A. Yes.
MR. ZONIES: Object to the form.
Q. And, Doctor, I just want to briefly go through a few things in this statement.
A. Okay.
Q. Do you see, under "Justification" for the position statement --
A. I do.
Q. And we're not going to read every line of this document, don't worry. But I do want to hit the high points here.
You see, under number 1, "Polypropylene material is safe and effective as a surgical implant"?
Did I read that correctly?
A. You did.
Q. And do you --
MR. ZONIES: Object to the form, object to this line of questioning, and the colloquy, as well.
Q. Doctor, do you agree with that assertion?
A. I do.
Q. And why do you agree with it?
A. Because all of the medical literature and my

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education, experience, and training supports this statement.

Q. And, Doctor, what is justification number 2 for this position statement?

A. "The monofilament polypropylene mesh midurethral sling is the most extensively studied anti-incontinence procedure in history."

Q. And, Doctor, do you agree with that assertion?

A. I most certainly do.

Q. And were you aware of the --

MR. ZONIES: Object to the form and reading from these papers.

Q. And, Doctor, were you aware of that fact prior to the issuing of your report in this case?

A. Yes.

Q. And, Doctor, in terms of the -- one second -- what is the third justification point?

A. "Polypropylene mesh midurethral slings are a standard of care for the surgical treatment of stress urinary incontinence and represent a great advance in the treatment of this condition for our patients."

Q. And, Doctor, is that something that you agree with?

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A. For sure.

MR. ZONIES: Object to the form.

A. For sure.

Q. And, Doctor, is that something that you agreed with when you were forming your opinions in this case and writing your report in Wave 2?

A. Yes.

MR. ZONIES: Object to the form, foundation.

Q. And, Doctor, you mentioned earlier that there were a number of organizations that had endorsed this position statement. I believe you testified that AUGS and SUFU were two of them.

Are there any others?

A. Yes. AAG --

MR. ZONIES: Objection.

A. -- AAGO, which is the American Association of Gynecologic Laparoscopists; ACOG, which is the American College of Obstetrics and Gynecology; NAFC, which is the National Association For Continence, NAFC; and SGS, which is the Society of Gynecologic Surgeons.

Q. Are you aware of any professional society that has recommended that pelvic floor surgeons not use midurethral slings like TVT-O?

A. I'm not aware of one.

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Q. Doctor, you were asked a number of questions about the success rates of TVT and, I think specifically, TVT-O.

Do you remember those questions?

A. Yes.

Q. And if I could refer your attention -- I'll give you your report back.

A. Okay.

Q. If I could refer your attention to page 19.

A. Okay.

Q. And, Doctor, do you see where you have cited a number of long-term TVT-O studies?

A. Yes, I do.

Q. And do you see where, in your report, you report that these studies show low complication rates?

Do you see that?

A. Yes.

(Exhibit 20 marked for identification.)

BY MR. WALKER:

Q. Doctor, I'm going to hand you what I'm marking as Exhibit No. 20. And this is one of the studies that you would cite -- that you cite in your report.

Do you recognize this study?

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A. Yes.

Q. And what is that study?

A. "Seven years of objective and subjective outcomes on... (TVT-O) vaginal tape: Why do tapes fail?" It's from the urogyn department in Athens, Greece.

Q. And, Doctor, what were the conclusions of this study?

A. Conclusion was "The TVT-O procedure provides a high objective and subjective long-term efficacy, a clinically meaningful improvement to patient quality of care, and an excellent safety profile. Concomitant vaginal hysterectomy and apical compartment prolapse (are) associated with a higher risk for objective and subjective failure."

Q. And, Doctor, is this a report that you reviewed and relied upon?

A. Yes.

(Exhibit 21 marked for identification.)

BY MR. WALKER:

Q. Doctor, I'm going to hand you what I'm marking as Exhibit No. 21.

Do you recognize this article?

A. I do.

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Q. And what is it?
A. It's a "Five-year Results of Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress (urinary) Incontinence" from the group in Finland, Dr. Nilsson.
Q. And, Doctor, what was the objective cure rate in this study for the TVT-O?
A. The objective cure rate was greater than 80 percent.
Q. And I'll direct your attention to the results and limitations paragraph --
A. Um-hmm.
Q. -- of the abstract.
A. Um-hmm.
Q. Do you see that?
A. Yes, I do.
Q. According to that, what was the specific objective cure rate for the TVT-O?
A. Objective cure rate was 86.2 percent in the TVT-O group.
Q. And then what was the subjective satisfaction, as reported for the TVT-O group?
A. 91.7 percent.
Q. And is this a study that you reviewed and

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relied upon when you formed your opinions in this case?
A. I did.
(Exhibit 22 marked for identification.)
BY MR. WALKER:
Q. Doctor, I'm going to hand you what I am marking as Exhibit No. 22.
Do you recognize this study?
A. Yes, I do.
Q. What is it?
A. "TVT-O for the Treatment of Pure Urodynamic Stress Incontinence: Efficacy, Adverse Effects, and Prognostic Factors at 5-Year Follow-Up." And this is from the Italian group and a group in France.
Q. And, Doctor, if you'll refer to the results and limitations section, what were the subjective and objective cure rates for the TVT-O --
A. The --
Q. -- at five years?
A. Yeah. The five-year subjective/objective was 90.3 percent and 90.8 percent, respectively.
Q. And is this a study that you reviewed and relied upon when you formed your opinions in --
A. I did.
Q. -- this case?

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A. I did.
Q. And what significance, if any, is there, in your opinion, to long-term data on a surgical product?
A. I think long-term data gives you more basis for forming the opinion that it is a safe and effective treatment.
Q. And, Doctor, there was some questions about the TOMUS study.
Did you, in fact, review and rely on the TOMUS study --
A. I did.
Q. -- in the preparation of your opinions?
A. I did.
Q. Okay. And do you recall generally, without it being in front of you, what the conclusions were in the TOMUS study with respect to the safety and efficacy of TVT-O?
A. I think it was --
MR. ZONIES: Object to the form.
A. -- comparing the TVT-O and the TVT. And the only clinical significance that was different was that the TVT had more -- retropubic TVT had more bladder injuries.
Q. You recall I asked you earlier about the

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spectrum of evidence you consider when forming your opinions?
A. Yes.
Q. What types of evidence are at the highest end of that spectrum?
A. Those would be meta-analyses, randomized control trials. Those would be the highest.
Q. And do you remember that you were asked a number of questions about whether or not you had read various Ethicon company witness depositions?
A. Yes.
Q. Where would you place depositions of a company witness on that spectrum of evidence?
A. At the bottom.
MR. ZONIES: Object to form.
Q. And why would you place it at the bottom?
MR. ZONIES: Same objection.
A. Because, as scientists, we have to rely on the scientific data, and the scientific data has to be generated by controlled studies and meta-analyses and well-controlled studies. And these are just depositions from employees.
Q. And in your review of not just Ethicon documents, but from all of the medical literature, to

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include randomized control trials and meta-analyses, what has that informed you, in terms of the safety or efficacy of TVT-O?

A. I think it's one of the most safe midurethral slings that we have.

Q. Doctor, do you remember there were some questions asked about the incidence of groin pain following a TVT-O?

A. I do.

Q. And I think you recall being shown Exhibit 18, which is the 2015 Cochrane Review?

A. Yes.

Q. And what is the 2015 Cochrane Review?

A. The Cochrane Review is the extensive review of the literature on a specific topic, which in this case would be midurethral slings.

Q. And you would agree, it's a meta-analysis?

A. It is definitely a meta-analysis.

Q. Now, I've got the marked copy, Exhibit 18.

A. Okay.

Q. And I think you've got a copy --

A. Yep.

Q. -- in your binder. Look for the --

A. I think it's the biggest one right there.

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Q. Yeah, look for the thick tab.

A. Yeah, there it is.

Q. Make sure it's 2015, though --

A. Yeah.

Q. -- because I want to make sure we're on the same page.

A. Yep.

Q. Okay, good.

So with respect to groin pain, Dr. Karram, I want to direct your attention to page 28.

A. Okay.

Q. And do you see, Doctor, there's a discussion on page 28 about pain, specifically groin pain?

A. There is.

Q. And what was the conclusion of the Cochrane meta-analysis, with respect to groin pain and obturator slings?

A. "There was a significant higher occurrence of groin pain in women who underwent the transobturator procedure than in women who underwent the retropubic procedure."

Q. And what were the rates?

A. The rates were -- let me see -- 4.5 percent -- 4.51 percent and -- yeah, that was it.

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Q. And what were the findings with regards to suprapubic pain and the transobturator procedure?

A. "Both groin pain and suprapubic pain occurrence were short lasting with most resolving within the first six months."

Q. With which procedure, retropubic or obturator, did the Cochrane analysis, in 2015, find a higher rate of suprapubic pain?

A. With the retropubic.

Q. Do you see, Doctor, on that third line, where it says "Analysis 1.24"?

A. Yes.

Q. All right. I want to direct your attention to page 200.

A. Um-hmm.

Q. And would you agree that this is a table, on page 200, that is reflecting Analysis 1.24?

A. Yes.

Q. And what is this table?

A. It's a comparison of transobturator versus retropubic outcome, 26 repeat incontinence surgeries --

Q. And, Doctor --

A. -- in one year.

Q. Sorry to interrupt.

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A. That's okay.

Q. And just to be clear, did you review and rely on the 2015 Cochrane Review, when you were writing your report and forming your opinions regarding TVT-O?

A. I did.

Q. And do you see that this lists a number of different studies?

A. Yes.

Q. And do you see that it even includes the Teo study you were asked about?

A. Yes.

Q. And, Doctor, looking at the various studies --

A. Um-hmm.

Q. -- that are reflected in this table, would you agree that you find, in some of these studies, a relatively low rate of groin pain in the obturator route? Is that correct?

A. That's correct.

MR. ZONIES: Object to the form.

Q. And when I say a "relatively low rate," Doctor, what does that mean to you?

MR. ZONIES: Same objection.

A. That would mean that it's acceptable as a

possible risk and lower than -- well, just that it's acceptable risk.

Q. Doctor, you were asked a number of questions about the suitability of using an obturator sling in an ISD patient. Do you remember those questions?

A. Yes.

Q. Generally speaking, when you are deciding whether or not a particular sling would be appropriate for an ISD patient, what are the various clinical factors that you consider when making that decision?

A. If the patient has had a previous sling; if she's had multiple abdominal surgeries; if she is obese; if she's had a previous hysterectomy; and the -- if you can possibly identify the cause of her ISD.

Q. And, Doctor, what is your basis for knowing that those are various factors that should be considered when making that clinical assessment?

MR. ZONIES: Object to the form.

A. My education, experience, and training, and the medical literature.

Q. I think you have the reliance list.

A. I do.

Q. Can you hand it to me?

A. Um-hmm.

Q. Okay. Doctor, look at this with me, if you will --

A. Okay.

Q. -- since we're working off the same copy.

A. Um-hmm.

Q. This is your reliance list for your TVT-O report; correct?

A. Correct.

Q. All right. And I think you were asked questions about that first section of the reliance list, which contains medical literature. Is that correct?

A. That's it.

Q. Approximately, Doctor, what percentage of your reliance list is comprised of medical literature as opposed to company documents and public --

A. I would say --

Q. -- documents?

A. -- oh -- two-thirds.

Q. And, Doctor, have you reviewed the medical literature that's contained in this first two-thirds of your reliance list?

A. I have reviewed or read, or read abstracts of, almost all of these, yes.

Q. And that is a function not just of the last few months, but a function of what you've read and reviewed over the course of your career; is that correct?

A. That's correct.

Q. And, Doctor, when you assess the totality of that literature, what is your opinion regarding the safety and efficacy of TVT-O?

A. I agree with the AUGS position statement. It's a safe, effective procedure, and we should continue using it.

MR. WALKER: Nothing further.

MR. ZONIES: Doctor, thank you very much for your time.

THE WITNESS: Thank you.

THE REPORTER: Signature, Doctor, for this deposition?

THE WITNESS: Sure.

DEPOSITION CONCLUDED AT 6:46 P.M.

CERTIFICATE

State of Ohio :
: SS
State at Large :

I, Teresa A. Moore, RPR, CRR, the undersigned, a duly commissioned notary public within and for the State of Ohio, do hereby certify that before the giving of his aforesaid deposition, MICHAEL KARRAM, M.D. was by me first duly sworn to depose the truth, the whole truth and nothing but the truth; that the foregoing is the deposition given at said time and place by MICHAEL KARRAM, M.D.; that said deposition was taken in all respects pursuant to stipulations of counsel; that I am neither a relative of nor employee of any of their parties or their counsel, and have no interest whatever in the result of the action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal of office on this 5th day of July, 2016.

TERESA A. MOORE
Notary Public - State of Ohio
My Commission expires: 06/17/21

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

MICHAEL KARRAM, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

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ERRATA

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